IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO

THE UNITED STATES OF AMERICA, and

THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, AND WASHINGTON; THE DISTRICT OF COLUMBIA; THE COUNTY OF ALLEGHENY; AND THE CITIES OF CHICAGO, NEW YORK, AND PHILADELPHIA,

ex rel. JOEL STEVENS

Plaintiffs,

v.

ATRICURE INC., ST. HELENA HOSPITAL, AND ADVENTIST HEALTH;

Defendants.

CASE NO. 1:22-cv-284-MRB

Judge Michael R. Barrett

MEMORANDUM IN SUPPORT OF ATRICURE'S MOTION TO DISMISS THE FOURTH AMENDED COMPLAINT

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The Sixth Circuit imposes a strict requirement that a *qui tam* relator identify "an actual false claim with particularity." *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 879 (6th Cir. 2006). To withstand Rule 9(b) scrutiny, a relator "must provide specific examples of claims submitted to the government." *U.S. ex rel. SNAPP, Inc. v. Ford Motor Co.*, 532 F.3d 496, 506 (6th Cir. 2008). Describing an alleged fraudulent scheme with particularity, and assuming it resulted in the submission of false claims, is not enough. *U.S. ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905, 914–15 (6th Cir. 2017).

Relator has not identified a single claim for payment that was submitted to the Government. Instead, Relator alleges that two doctors performed or scheduled surgeries, some of which involved the alleged use of AtriCure medical devices. Because their patients were allegedly eligible for Government-sponsored healthcare, Relator assumes some false claim for payment must have been made. But eligibility for Government-sponsored healthcare does not satisfy the requirement that Relator identify an actual claim submitted for payment. *See id.* at 921. Nor has Relator alleged any factual support to identify such a claim with the requisite particularity (*e.g.*, who submitted such a claim, when, or whether it was paid). *Cf. U.S. ex rel. Sheoran v. Wal-Mart Stores E., LP*, 858 F. App'x 876, 879 (6th Cir. 2021) ("Under Rule 9(b), specifics on presentment are required, such as the types of employees involved and the specific dates underlying the claims.").

The Sixth Circuit has relaxed the stringent 9(b) standard only once under circumstances that do not apply. In *U.S. ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, a relator with "personal knowledge of [the defendant's] billing practices" was able to allege specific facts "supporting a strong inference that particular identified claims were submitted." 838 F.3d 750, 771 (6th Cir. 2016). The relator's job was to prepare the defendant's reimbursement paperwork and, although she did not personally submit claims to the Government, she received confirmation

after the fact that claims had been submitted. *Id.* at 756–59. Under those circumstances only, the Sixth Circuit accepted an inference that claims had in fact been made. *Cf. U.S. ex rel. Hirt v. Walgreen Co.*, 846 F.3d 879, 881 (6th Cir. 2017) ("In practice, we have applied the 'relaxed' standard just once, and that application has no purchasing power here.").

Relator does not have, or claim to have, personal knowledge of any healthcare providers' billing practices, rendering the one-time *Prather* exception categorically inapplicable. *See Ibanez*, 874 F.3d at 916 ("In order for the *Prather* exception to apply, it is not enough to allege personal knowledge of an allegedly fraudulent scheme; a relator must allege adequate personal knowledge of billing practices themselves.").

Because Relator alleges Defendants violated the False Claims Act ("FCA") by violating the Anti-Kickback Statute ("AKS"), the Complaint must not only state a plausible FCA claim, but also a particularized AKS violation as well. *U.S. ex rel. Antoon v. Cleveland Clinic Found.*, 978 F. Supp. 2d 880, 893 (S.D. Ohio 2013). "To prove a violation of the AKS, Relator must show: (1) remuneration offered or paid; (2) in order to induce the referral of government healthcare business; (3) done knowingly and willfully." *U.S. ex rel. McDonough v. Symphony Diagnostic Servs., Inc.*, 36 F. Supp. 3d 773, 777 (S.D. Ohio 2014) (citing 42 U.S.C. § 1320a-7b(b)(2)(B)). Moreover, Relator must show a "connection" between the alleged kickback scheme and an actual claim for payment. *Ibanez*, 874 F.3d at 915–16.

The Complaint has not pleaded any AKS violation, much less with particularity, and Relator has shown no such connection.

For purposes of the AKS, remuneration excludes services or products that provide "no substantial independent value to the purchaser," such as equipment that can only be used in conjunction with purchased products, "billing assistance tailored to the purchased products, reimbursement consultation," and the like. *U.S. ex rel. Suarez v. AbbVie Inc.*, No. 15 C 8928, 2019 WL 4749967, at *7 (N.D. Ill. Sept. 30, 2019) (quoting OIG guidance). The Complaint alleges that AtriCure provided exactly such product-related services, which do not have "independent" value and are thus not remuneration. Furthermore, the Complaint's generalized allegations that AtriCure provided "free services" or sponsored "events"—without identifying who attended or received them, when they took place, or what they were allegedly worth—do not satisfy Rule 9(b). *Cf. Jones-McNamara*, 630 F. App'x at 402.

Compensation (or "remuneration") is only a kickback if the defendant offered it to induce the referral or purchase of a product. 42 U.S.C. § 1320a-7b(b)(2)(A)–(B); *accord Jones-McNamara*, 630 F. App'x at 400 (noting the "gravamen of Medicare fraud is inducement").

"Ordinarily, where all federal claims have been dismissed, federal courts should decline to exercise supplemental jurisdiction over state law claims." *Reynosa v. Schultz*, 282 F. App'x 386, 391 (6th Cir. 2008); *accord Antoon*, 978 F. Supp. 2d at 894 ("When all federal claims are dismissed before trial, the balance of considerations usually will result in dismissal of the state-law claims. That would be the case here."). Accordingly, even if a state or local claim could withstand dismissal, the Court should decline to exercise supplemental jurisdiction over it.

This is Relator's fifth attempt to state a viable claim for relief, including Relator's most recent amendment undertaken specifically to address this Circuit's rigorous standards. Because further amendment would be futile, the Complaint should be dismissed with prejudice. *See Layer-Rosario v. Allied Mortg. Cap. Corp.*, No. 17-5468, 2018 WL 1989636, at *3 (6th Cir. Jan. 9, 2018) ("Amendment of a complaint is futile when the proposed amendment would not permit the complaint to survive a motion to dismiss."); *Daniels v. Morgan Asset Mgmt., Inc.*, 497 F. App'x 548, 555 (6th Cir. 2012) ("[B]ecause this proposed amendment would be Plaintiffs' third failed attempt to file an action that is not precluded by SLUSA, the district court did not abuse its discretion in dismissing Plaintiffs' suit with prejudice.").

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INTRODUCTION

The *sine qua non* of the False Claims Act ("FCA") is the actual submission of a claim for payment. At the pleading stage, that standard is "stringent: where a relator alleges a complex and far-reaching fraudulent scheme, in violation of [the FCA], it is insufficient to simply plead the scheme; he must also identify a representative false claim that was actually submitted to the government." *U.S. ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905, 914 (6th Cir. 2017);[1] *accord U.S. ex rel. Eberhard v. Physicians Choice Lab'y Servs., LLC*, 642 F. App'x 547, 550 (6th Cir. 2016) ("In assessing FCA claims under Rule 9(b), our Circuit imposes a strict requirement that relators identify actual false claims."); *U.S. ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 504 (6th Cir. 2007) ("We hold that pleading an actual false claim with particularity is an indispensable element of a complaint that alleges a FCA violation in compliance with Rule 9(b)."); *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 879 (6th Cir. 2006) (affirming dismissal where relator was "unable to identify a specific claim submitted directly to the United States by the defendant"). Relator's Complaint fails to meet that standard.

Relator is a salesperson who alleges that his former employer, AtriCure Inc., violated the FCA and various state and local equivalents. In a convoluted chain of causation, Relator contends AtriCure's relationships with healthcare providers constituted bribes, which may have resulted in improper surgeries, some of which may have been reimbursable by a state or federal program, and which therefore may have culminated in the submission of false claims for payment to the Government. Relator is wrong, and it is unsurprising that the Department of Justice and every state and municipality named in Relator's Complaint have declined to intervene in this case.

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[1] Throughout this brief, internal quotations, citations, and alterations have been omitted, and all emphasis has been added unless otherwise noted.

AtriCure's training and educational initiatives are not kickback schemes—they are critical steps in a process designed to improve the safety and efficacy of complicated surgeries. And Relator's conclusory allegations that these initiatives were bribes, intended to induce the purchase of AtriCure devices, fail to support a plausible claim. Moreover, and more fundamentally, Relator does not identify a single allegedly false claim that was actually submitted for payment to a Government program. As a medical device company, AtriCure does not perform surgeries or submit related claims for payment to the Government. And, as a former AtriCure salesperson, Relator had no access or insight into the claims for payment that hospitals ultimately submit. Because the Complaint does not identify a claim for payment, much less a claim that was fraudulent or false, Relator's Fourth Amended Complaint should be dismissed with prejudice. *See Ibanez*, 874 F.3d at 915–16 ("Relators allege knowledge of a complex scheme related to the promotion of Abilify, but they do not provide any representative claim that was actually submitted to the government for payment.… [A]bsent a representative false claim derived from the alleged promotional scheme, the second amended complaint fails to adequately plead a violation[.]").

BACKGROUND

A. Surgical Ablation and Treatment of Atrial Fibrillation

AtriCure is a Mason, Ohio-based manufacturer of innovative surgical devices used in the treatment of atrial fibrillation ("Afib") and other surgical procedures. Afib is an abnormal heart rhythm caused by erratic electrical signals in the heart. Compl. ¶ 55. Afib is the most commonly diagnosed arrhythmia and, left untreated, causes physical changes to the structure and shape of the heart that can lead to serious health problems, including heart failure and stroke. *See id*.

Although Afib can be managed with medications in its earliest stages, it is a progressive disease that will ultimately require additional interventions for many patients. *See generally id.* at n.1. Cardiac ablation is the interventional treatment of relevance to this case and involves the use

of an energy source to burn, or "ablate," cardiac tissue in precise patterns. *See id.* ¶ 57. Ablation creates scar tissue that is not electrically conductive and, therefore, interrupts the erratic electrical signals that cause Afib. *See id.* ¶ 56.

There are different kinds of cardiac ablation. In a catheter ablation, an electrophysiologist ("EP") inserts a thin, flexible device into a patient's vein and guides it through the vein into the heart. *See id.* ¶¶ 57, 76. Once in the heart, a small electrode in the tip of the catheter is used to ablate tissue from the inside. *See id.* ¶ 76. Surgical ablation is similar but is performed by a cardiothoracic surgeon with surgical tools instead of catheters. *See id.* ¶ 60. The surgeon accesses the patient's heart via incisions in the chest wall or sternum and applies the ablation energy mainly to the outside surfaces. *Id.* Patients may undergo surgical ablation because they have failed other treatments, because they have advanced disease that cannot be treated via a catheter ablation, or because they are already scheduled for heart surgery to treat another condition, and the ablation can be performed at the same time. Each of these approaches to treatment—catheter ablation and surgical ablation—has advantages and disadvantages.

A third approach, known as hybrid therapy, involves a collaboration between a surgeon and an EP that combines elements of both approaches. It can be difficult for ablation energy to penetrate all the way through heart tissue when treating from just the inside (catheter) or outside (surgical). Hybrid therapy treats both the inside and outside of the heart.

B. AtriCure Solicits Expert Training and Feedback

For twenty years, AtriCure has worked with surgeons to develop the devices they need to perform successful cardiac ablation and to develop and test procedures using those devices. AtriCure's surgical devices include (a) clamps that transmit radiofrequency energy to create long linear ablations on cardiac tissue; (b) pens and probes that transmit radiofrequency energy to create smaller linear or spot lesions; (c) the COBRA Fusion device family, which combines

radiofrequency energy with suction to gently pull the tissue targeted for ablation into the device and out of the path of circulating blood; (d) the EPi-Sense coagulation system, which ablates tissue on the backside of the heart using radiofrequency energy; and (e) cryo-ablation probes that freeze, rather than burn, cardiac tissue. *See id.* ¶¶ 73–74.

Surgical ablation of the heart is a complex procedure that, while emerging as a recognized standard of care in the last decade, is not commonly taught in medical school or even in cardiothoracic surgical residency programs. Accordingly, much of the burden for training the medical community as to how to use its surgical devices safely falls on AtriCure. To that end, AtriCure has relationships with doctors who are recognized as experts in this field and who perform these complex procedures regularly. These individuals are uniquely qualified to train their peers through lectures, demonstrations, case observations and proctoring; to offer feedback to AtriCure about what instruments they need to achieve successful outcomes; and to participate in clinical trials evaluating AtriCure's devices. Partnering with the practitioners and organizations that are most knowledgeable about Afib facilitates better patient outcomes, which is in everyone's shared best interests.

C. Relator Files a *Qui Tam* Action Against AtriCure

Relator filed his original Complaint on January 10, 2017, a First Amended Complaint on June 4, 2020, and a Second Amended Complaint on December 30, 2020. Case No. 3:17-CV-00010 (W.D.N.C.), ECF Nos. 1, 24, 28. On March 15, 2021, after investigating Relator's claims, the federal Government informed the court that it and every relevant state and local entity were declining intervention, and this case was unsealed. W.D.N.C. ECF Nos. 29 and 30. Relator filed a Third Amended Complaint on August 6, 2021, withdrawing a number of claims and theories. W.D.N.C. ECF No. 51. On October 12, 2021, Magistrate Judge David Cayer found that this case had "no connection" to the Western District of North Carolina and granted AtriCure's motion to

transfer to the Southern District of Ohio, the district encompassing its headquarters and manufacturing facilities in Mason, Ohio. W.D.N.C. ECF No. 65. Relator's appeal of that Order was rejected, and the case was docketed in this Court on May 24, 2022. S.D. Ohio ECF No. 70. Relator filed a Fourth Amended Complaint on July 12, 2022, S.D. Ohio ECF No. 88 (referred to herein as the "Complaint" for ease of reference), "to address issues arising from the change of venue," *see* S.D. Ohio ECF No. 86 at PageID 56.

In its current form, the Complaint now alleges that AtriCure paid illegal kickbacks to healthcare providers in exchange for using or referring AtriCure devices, in violation of the federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b). Compl. ¶¶ 3–4. By virtue of those alleged kickbacks, the Complaint asserts that AtriCure caused healthcare providers to submit fraudulent claims for payment to the Government, in violation of Section 3729(a)(1)(A) of the FCA (Count One); caused healthcare providers to make false records or statements that were material to false or fraudulent claims in violation of Section 3729(a)(1)(B) of the FCA (Count Two); and conspired with healthcare providers to violate the FCA in violation of Section 3729(a)(1)(C) (Count Three). Counts Four through Thirty-Seven allege comparable violations of various state and local laws. For the reasons below, Relator's Complaint does not allege any plausible FCA violation and must be dismissed.

LEGAL STANDARDS

A complaint must give a defendant "fair notice of what the … claim is and the grounds upon which it rests." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Plaintiffs cannot discharge their obligation by reciting "labels and conclusions," or providing a "formulaic recitation of the elements of a cause of action." *Id.* Rather, to survive a motion to dismiss, a complaint must allege "sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Kreipke v. Wayne State Univ.*, 807 F.3d 768, 782 (6th Cir. 2015). "Where a complaint

pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *U.S. ex rel. Harper v. Muskingum Watershed Conservancy Dist.*, 842 F.3d 430, 438 (6th Cir. 2016).

"Complaints alleging FCA violations must comply with Rule 9(b)'s requirement that fraud be pled with particularity." *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 466 (6th Cir. 2011). The particularity standard is "stringent," *Ibanez*, 874 F.3d at 914, and "demands specifics"—a relator cannot rely on "inferences and implications" to satisfy the heightened pleading standard imposed by Rule 9(b), *U.S. ex rel. Hirt v. Walgreen Co.*, 846 F.3d 879, 881 (6th Cir. 2017). Rather, "where a relator pleads a complex and far-reaching fraudulent scheme, she also must provide examples of specific false claims submitted to the government pursuant to that scheme in order to proceed to discovery[.]" *Ibanez*, 874 F.3d at 914.

Together, Rules 12(b)(6) and 9(b) serve an important gatekeeping function. Rule 12(b)(6) "enable[s] defendants to challenge the legal sufficiency of the complaint without subjecting themselves to discovery." *Eberhard*, 642 F. App'x at 554. And "the purpose of Rule 9(b)'s heightened pleading standard is to prevent fishing expeditions." *Id.* Rule 9(b) thus prevents relators from suing based on speculation and using discovery to search for support for otherwise inadequate allegations. *See U.S. ex rel. Marlar v. BWXT Y-12, L.L.C.*, 525 F.3d 439, 445 (6th Cir. 2008) (noting Rule 9(b)'s utility in light of the fact that "[c]laims of fraud raise a high risk of abusive litigation"); *Green v Amerisource Bergen Corp.*, No. 4:15-CV-379, 2017 WL 1209909, at *4 (S.D. Tex. Mar. 31, 2017) (noting a primary purpose of 9(b) is to "eliminate fraud actions in which all the facts are learned after discovery"). A FCA complaint, like this one, that fails to meet each pleading standard must be dismissed.

ARGUMENT

The FCA "is an anti-fraud statute that prohibits the knowing submission of false or fraudulent claims to the federal government." *U.S. ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 342 F.3d 634, 640 (6th Cir. 2003). "To establish a claim under the FCA, a plaintiff must allege that (i) the defendant presented [or caused to be presented] a claim of payment to the government, (ii) the claim was false or fraudulent, (iii) the defendant knew it was false or fraudulent, and (iv) the false claim was material to the government's payment." *U.S. ex rel. Sheoran v. Wal-Mart Stores E., LP*, 858 F. App'x 876, 878 (6th Cir. 2021). A claim for payment "resulting from" an illegal kickback is false. *Jones-McNamara v. Holzer Health Sys.*, 630 F. App'x 394, 400 (6th Cir. 2015). To allege such a theory of FCA liability, a relator must allege both a plausible FCA violation and a plausible AKS violation—and both must meet the heightened pleading standards imposed by Rule 9(b). *See U.S. ex rel. Antoon v. Cleveland Clinic Found.*, 978 F. Supp. 2d 880, 893 (S.D. Ohio 2013), *aff'd on other grounds*, 788 F.3d 605 (6th Cir. 2015). Relator's Complaint does not satisfy these standards.

First, where exactly is the false claim? In a sea of allegedly wrongful conduct, the Complaint does not identify a single claim that was actually submitted to the Government for payment. *Second*, the Complaint does not adequately allege that any even theoretical claim was fraudulent or false. The Complaint does not properly allege an illegal kickback scheme: it offers no factual matter whatsoever to support the conclusory—and false—allegation that AtriCure's educational grants, training programs, and device-related support were bribes. Nor does the Complaint tie an alleged kickback to any claim. It is not enough to allege a kickback scheme on one hand and the submission of claims for payment on the other—falsity, under Relator's theory of liability, requires an illegal kickback to have actually resulted in a submitted claim. Because the Complaint fails completely to allege an illegal FCA/AKS scheme, Counts One and Two are

not viable and must be dismissed. Count Two, Relator's false records claim, must be dismissed for the additional reason that the Complaint does not even attempt to identify any false record that was "material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B).

The Complaint's attendant claims are likewise defective. Because the Complaint does not adequately plead a FCA violation, Count Three, Relator's conspiracy claim, necessarily fails. And it also fails for the independent reason that the Complaint does not plead an agreement between AtriCure and another to violate the FCA. Counts Four through Thirty-Seven, Relator's state and local law claims, fail for similar reasons. Because those jurisdictions' FCA equivalents are adjudicated under the same standards as the federal FCA, failure to plead a viable federal claim requires dismissal of the state and local claims as well. Moreover, the Complaint does not allege any conduct whatsoever in most of the jurisdictions as to which it asserts a claim, including any surgery that could have culminated in even the theoretical submission of a claim. For all of these reasons, the Complaint should be dismissed in its entirety.

I. COUNTS ONE AND TWO MUST BE DISMISSED BECAUSE THE COMPLAINT FAILS TO IDENTIFY ANY CLAIM FOR PAYMENT

There are two schools of thought regarding Rule 9(b)'s pleading requirements for a FCA claim. On the one hand are jurisdictions that permit a plaintiff "to allege particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Eberhard*, 642 F. App'x at 550 (reciting the First, Third, Fifth, and Ninth Circuit standard). On the other are jurisdictions that require a plaintiff to identify an actual, representative claim. *Id*. The Sixth Circuit belongs to the second group. *See id.*; *see also Bledsoe*, 501 F.3d at 505 n.13 (joining the Fourth, Eighth, and Eleventh Circuits and finding the alternative interpretation "cannot be reconciled with the language of Rule 9(b) and the FCA").

Rejecting the contention that a FCA complaint may infer the submission of an actual claim

for payment, the Sixth Circuit has confirmed that "particularized allegations of an actual false claim is an indispensable element of a FCA violation, and must be specifically pled if a complaint is to survive Rule 9(b) scrutiny." *Bledsoe*, 501 F.3d at 505. Thus, no matter how robustly a complaint describes a predicate scheme, if it does not identify "which specific false claims constitute a violation of the FCA," it must be dismissed.[2] *Id.*; *accord Walgreen*, 846 F.3d at 881 ("[Relator] has not met the [Rule 9(b)] standard. His complaint does not identify a single false claim."); *U.S. ex rel. SNAPP, Inc. v. Ford Motor Co.*, 532 F.3d 496, 506 (6th Cir. 2008) ("Despite the requirement that Relator must provide specific examples of claims submitted to the government as part of Ford's alleged fraudulent scheme, Relator does not provide a single example of a specific claim made by Ford."); *Yuhasz v. Brush Wellman, Inc.*, 341 F.3d 559, 563 (6th Cir. 2003) (same).

The requirement that a relator identify an actual false claim with particularity applies to both Counts One and Two of the Complaint. Count One requires proof that a "false or fraudulent claim was 'presented' to the government," requiring both the identification of a claim and specific factual allegations that it was presented for payment. *Ibanez*, 874 F.3d at 914; *see also Wal-Mart*, 858 F. App'x at 878 ("Under Rule 9(b), specifics on presentment are required, such as the types of employees involved and the specific dates underlying the claims."). Count Two does not require proof of presentment specifically, *see Allison Engine Co. v. U.S. ex rel. Sanders*, 553 U.S. 662, 671 (2008), but a false records claim still must "plead a connection between the alleged fraud and an actual claim made to the government," *Chesbrough*, 655 F.3d at 473. Identifying "at least one false claim with specificity is [thus] an indispensable element" of both Counts One and Two of the Complaint. *Walgreen*, 846 F.3d at 880.

[2] For the avoidance of doubt, the Complaint also fails under the 9(b) standard used in the First, Third, Fifth and Ninth Circuits, as it does not include particular details of a scheme to submit false claims paired with reliable indicia that supports any inference—let alone a strong one—that claims were actually submitted.

A. The Complaint fails to meet the Court's stringent Rule 9(b) standard

Relator's Complaint is plainly inadequate. After more than 200 paragraphs describing AtriCure's alleged promotional activities, the Complaint baldly assumes that they culminated in the submission of claims. But it is well-established, and determinative, in this Circuit that such speculation does not support a plausible claim.

The Sixth Circuit has held firm that "Rule 9(b) does not permit a False Claims Act plaintiff merely to describe a private scheme in detail but then to allege simply that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government." *Sanderson*, 447 F.3d at 877; *accord Eberhard*, 642 F. App'x at 553 ("[Relator] asks that we assume, on the basis of speculation, that claims requesting illegal payments must have been submitted…. Rule 9(b) does not permit such speculation."); *U.S. ex rel. Hockenberry v. OhioHealth Corp.*, No. 16-4064, 2017 WL 4315016, at *2 (6th Cir. Apr. 14, 2017) ("Although the complaint alleges that [defendants] engaged in a long-term scheme to defraud Medicare by upcoding for critical-care services, [relator's] concession that he cannot identify an actual false claim that the defendants submitted for payment or approval is fatal to his FCA claims."). Relator's reliance on inferences alone forecloses his FCA claims.

By and large, Relator relies on the fact that AtriCure made sales in certain jurisdictions to allege that claims for payment from the Government must have been made. Specifically, the Complaint alleges that: (1) four AtriCure sales representatives had territories that included hospitals in "parts of California" and "parts of Oregon, Washington state and Idaho," Compl. ¶ 219; (2) those representatives generated about $900,000 in quarterly sales, *id.* ¶ 220; and (3) Medicare reimburses for cardiac ablation procedures in general, *id.* ¶¶ 214–18. But the Complaint does not allege what AtriCure devices those representatives sold; whether those devices were used in surgical procedures; if so, by whom or when; whether the doctors or hospitals who

supposedly performed these procedures received an alleged kickback and, if so, in what form; and—critically—whether any doctor or hospital in the listed territories submitted a specific claim for reimbursement to the Government. The Complaint simply assumes, because AtriCure made sales, that some unnamed devices may have been used in surgeries, which may have resulted from kickbacks, and may have been submitted to the Government for reimbursement. The Sixth Circuit has soundly rejected such speculative leaps.

In *Ibanez*, the Sixth Circuit affirmed dismissal of a FCA complaint based on an alleged kickback scheme where the relators did not identify a false claim and only assumed one must have been made. 874 F.3d at 915. The relators, former pharmaceutical sales representatives, alleged that their employer had improperly promoted a drug for off-label uses, and provided Medicaid reimbursement data to prove that prescriptions for the drug had been paid by the Government. *Id.* at 912, 920. The Sixth Circuit affirmed dismissal of their complaint. The court confirmed that a relator cannot allege a FCA claim without identifying "a representative false claim that was actually submitted to the government," and it described the "long chain of causal links" required to identify such a claim in a FCA/AKS complaint: a relator must allege facts demonstrating that (1) the defendant improperly promoted its product; (2) a healthcare provider purchased or prescribed the product "because of" the improper inducement; (3) a patient consummated the purchase or prescription; and (4) the healthcare provider then submitted "a claim to the government for reimbursement." *Id.* at 914–15. The relator must "describe[] each step with particularity: a prescription reimbursement submitted to the government for a tainted prescription." *Id.* at 915. "[I]dentifying a claim that merely infers one or more of these elements is inadequate." *Id.* at 920.

In this latest iteration of the Complaint—now Relator's fifth attempt to plead a plausible claim—Relator has added new allegations regarding a handful of individual alleged surgeries. No

doubt recognizing the fatal impact of this Circuit's Rule 9(b) precedents requiring specific representative claims, Relator alleges for the first time that certain doctors who received alleged kickbacks performed (or scheduled) surgery using AtriCure devices. *See* Compl. ¶¶ 237–54. But the Complaint continues to only assume that claims for reimbursement were consequently made.

Specifically, Relator alleges that in 2014, Dr. Tripathi performed "a procedure" using AtriCure devices on a patient born in 1934, making the patient "eligible for Medicare." *Id.* ¶ 239. Without any factual support whatsoever, Relator conclusorily "alleges that this patient was insured by Medicare throughout 2014, such that CMS was billed for the surgery." *Id.* The same pattern of assumptions pervades Relator's new allegations. *See id.* ¶¶ 245–46 (alleging Dr. Tripathi "scheduled" two surgeries in 2015 with patients born in 1941 and 1944; "Relator alleges that this patient was insured by Medicare throughout 2015, such that CMS was billed for the entire surgery, including for AtriCure's products"[3]); *id.* ¶ 249 (alleging Dr. Kumpati performed "a procedure" in 2015 on a patient born in 1946; "Relator alleges that this patient was on Medicare throughout 2014, such that CMS was billed for the surgery."); *id.* ¶ 254 (alleging a surgery was "scheduled" for Dr. Kumpati at a Veterans Affairs ("VA") hospital in 2015; "Relator alleges that this surgery occurred and that shortly thereafter, a claim for $1,995 was submitted to the United States").

Relator's continued failure to identify a "claim that was actually submitted to the government"—and reliance instead on the conclusory assumption that a claim was likely made—is fatal. *Ibanez*, 874 F.3d at 914. Consistent with the requirement that a well-pleaded complaint plead "facts" and not "conclusory allegation[s]," *Twombly*, 550 U.S. at 556–57, "declaratory statements … that Defendants 'billed Medicare for services covered by Medicare' and submitted 'false and/or fraudulent statements and claims to Medicare for reimbursement'" are not enough.

[3] Notably, Relator does not even allege that any AtriCure products were used during these two procedures—only that Dr. Tripathi, a heart surgeon, scheduled surgeries for heart patients. *See id.*

U.S. ex rel. Sharma v. Miraca Life Scis., Inc., 472 F. Supp. 3d 429, 444 (N.D. Ohio 2020). "Rather, Relator must set forth sufficient allegations demonstrating the factual basis for these statements[.]" *Id.*; *see also Wal-Mart*, 858 F. App'x at 878 ("Sheoran argues that because some of the payments were for $1-2, the patient must have received government reimbursement through Medicare or Medicaid. But Rule 9(b) requires far more than mere speculation."); *U.S. ex rel. Frazier v. IASIS Healthcare Corp.*, 812 F. Supp. 2d 1008, 1017 (D. Ariz. 2011) ("Frazier provides only conclus[ory] statements that IASIS submitted claims to Medicare …. For example, Frazier repeats for each patient that, 'IASIS submitted claims to Medicare for the treatment of Patient —.' Thus, even assuming that medically unnecessary procedures were performed on the identified patients, Frazier fails to plead any facts providing reliable indicia that IASIS thereafter submitted claims seeking federal reimbursement for such procedures.").

Relator's allegations that surgery patients were Medicare-eligible by virtue of age, and that someone therefore must have submitted a claim on their behalf, do not state a viable claim. To begin with, since 1980, Medicare has been a secondary payer only, which "means that if payment for covered services has been or is reasonably expected to be made by someone else, Medicare does not have to pay." *Stalley v. Methodist Healthcare*, 517 F.3d 911, 915 (6th Cir. 2008). Moreover, the fact that a patient is Medicare-eligible does not mean that a claim for reimbursement was actually submitted or paid. *See Ibanez*, 874 F.3d at 921 ("[R]elators allege that, because D.M. had been a Medicaid beneficiary for nearly all of his life, the prescription was reimbursed by Ohio Medicaid. But … we are not to simply assume a claim was presented to the government because relators say so."); *accord U.S. ex rel. Crockett v. Complete Fitness Rehab., Inc.*, 721 F. App'x 451, 459 (6th Cir. 2018) (affirming dismissal of FCA complaint where relator provided care specifically to Medicare patients but did not "allege with the particularity required by Rule 9(b) that a specific

false claim was [actually] submitted to the United States"); *United States v. Orthopedic All., LLC*, No. CV 16-3966, 2020 WL 6151084, at *7 (C.D. Cal. July 13, 2020) ("Again, the fact that many patients would qualify for Medicare, even coupled with the payment scheme and allegedly sham contracts, does not constitute reliable indicia that lead to a strong inference that claims were actually submitted.").[4]

Relator's lone VA hospital allegation fails for these reasons and more. Relator alleges that in 2015, "a surgery was scheduled for Dr. Kumpati" on behalf of an unnamed patient, for an unnamed procedure, at a VA hospital. Compl. ¶ 254. Relator further alleges that an "AtriCure Atriclip was pre-authorized for $1,995." *Id.* Relator then assumes that "this surgery occurred and that shortly thereafter, a claim for $1,995 was submitted to the United States to pay for this AtriCure product." *Id.* Relator does not allege who sought the pre-authorization or when, whether that person (presumptively a VA acquisition officer[5] and not Dr. Kumpati himself) was the alleged recipient of a kickback, whether the clip was in fact purchased, or—critically—any factual matter whatsoever to support the conclusory allegation that the surgery in fact took place. *See id.*; *cf. U.S. ex rel. Nicholson v. MedCom Carolinas, Inc.*, No. 21-1290, 2022 WL 2838813, at *6 (4th Cir. July 21, 2022) (affirming dismissal of FCA complaint alleging "Patient T.W. received an Integra Dermal Replacement Therapy graft … whereby VA care benefits paid for this graft utilized by Dr. Phillips in excess of $3,000.00. So much detail is missing from this allegation that it sounds like a neighbor's conversation only half overheard through the walls.").

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[4] Again, the Ninth Circuit falls on the other side of the Rule 9(b) divide, where "reliable indicia that lead to a strong inference that claims were actually submitted" are enough. *See Eberhard*, 642 F. App'x at 550. But it bears note that Relator's allegations are insufficient even under this separate standard.

[5] *See, e.g.*, https://www.va.gov/opal/fo/dbwva.asp (explaining that each VA facility purchases "most[] requirements for direct delivery through its local acquisition office"); https://www.fss.va.gov/index.asp (explaining that the VA satisfies its "healthcare acquisition needs" pursuant to a Federal Supply Schedule, pursuant to "contracts awarded to pre-approved vendors" under which the VA "negotiate[d] firm-fixed pricing"). In light of these publicly-available standards, Relator's allegations that Government programs paid list prices for each and every surgical device allegedly used in a procedure are not even facially plausible.

It goes without saying that Relator's further assumption that "a claim for $1,995 was submitted to the United States"—by an unnamed person, on an unnamed date—likewise does not pass muster. *Ibanez*, 874 F.3d at 921 ("[A]bsent any factual support for this allegation and lacking any identifying information on who may have submitted a claim to the government for the 2013 prescription, we are not to simply assume a claim was presented to the government because relators say so."); *see also Marlar*, 525 F.3d at 445–46 (finding relator failed to plead presentment with particularity where complaint "has not pleaded any facts regarding whether the alleged false claims were in fact submitted to the government. Instead, Ms. Marlar relies on the general allegation, 'on information and belief,' that BWXT submitted purported false claims to the government, and that DOE paid BWXT a fee that was based in part of the purported false claims"); *Wal-Mart*, 858 F. App'x at 878 ("Under Rule 9(b), specifics on presentment are required, such as the types of employees involved and the specific dates underlying the claims.").

At bottom, like many before him, Relator has attempted to foster the <u>appearance</u> of pleading with particularity by packing the Complaint with hundreds of paragraphs of allegations naming doctors, quoting emails, and describing alleged marketing initiatives. But none of those allegations describes an allegedly false claim for payment or the presentation of such a claim to the Government. The Sixth Circuit has made it clear that Rule 9(b) is not a sliding scale—a relator cannot withstand Rule 9(b) scrutiny by pleading a fraudulent scheme with particularity only to gloss over the submission of an actual claim. And the Sixth Circuit has specifically cautioned courts not to be fooled by similar prolix complaints. *See Sanderson*, 447 F.3d at 877 ("The complaint sets out at some length a description of the accounting methodology used by [defendant] in allocating corporate debt, even identifying some of the specific loans undertaken by [defendant] and future dates on which the notes and debentures securing those loans came

due…. Unfortunately for the plaintiff, there is no specific information about the filing of the claims themselves."); *Yuhasz*, 341 F.3d at 564 ("A plaintiff should not be able to avoid the specificity requirements of Rule 9(b) by relying upon the complexity of the edifice which he created.").

Because "pleading an actual false claim with particularity is an indispensable element of a complaint that alleges a FCA violation in compliance with Rule 9(b)," Counts One and Two of the Complaint must be dismissed. *Bledsoe*, 501 F.3d at 504.

B. Relator is not entitled to a relaxation of the Rule 9(b) standard

The Sixth Circuit has recognized a single exception to the "stringent" requirement that a complaint identify the "time, place and contents" of an actual claim, but that exception does not apply. In *U.S. ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, the Sixth Circuit acknowledged a long-standing "hypothesi[s]" that a relator could plead a plausible FCA violation without identifying a specific claim if the relator could "otherwise allege facts—based on personal knowledge of billing practices—supporting a strong inference that particular identified claims were submitted." 838 F.3d 750, 769–70 (6th Cir. 2016). For the first, and only, time in the Sixth Circuit's history, the *Prather* relator met that standard.

Marjorie Prather was a home-healthcare employee who alleged that her employer had submitted false claims for Medicare reimbursements by forging required certifications. *Id.* at 754–55. Although Prather did not personally submit the company's claims for reimbursement, her job was to review Medicare claims documentation for the sole purpose of obtaining reimbursement, after which she would deliver the documentation to the company's billing department for submission to the government. *Walgreen*, 846 F.3d at 881–82 (describing *Prather* complaint). In support of her FCA allegations, Prather identified dates of treatment for four specific patients, identified the dates on which physicians signed the requisite certifications, alleged the requests for anticipated payment and final payment were submitted (sometimes giving dates of submission for

one or both), and identified specific amounts of payment requested. *Prather*, 838 F.3d at 769–70. For hundreds of other patients, Prather was able to provide the start and end dates for treatment and "identifying information for the specific provider" that supplied it. *Id.* at 770. "Prather also received confirmation that the final claims that she reviewed were [in fact] submitted for payment." *Id.* On those specific facts, the Sixth Circuit found Prather had shown sufficient "personal knowledge of [the defendant's] billing practices," coupled with knowledge of "specific identified claims," to satisfy Rule 9(b) scrutiny. *Id.* at 771.

Subsequent decisions have emphasized the narrowness of the *Prather* exception. *See, e.g.*, *U.S. ex rel. Owsley v. Fazzi Assocs., Inc.*, 16 F.4th 192, 196 (6th Cir. 2021), *petition for cert. filed*, 2021 WL 6118289 (U.S. Dec. 21, 2021) (No. 21-936) (explaining relator could satisfy 9(b) in only "one of two ways"—either by identifying a "representative claim that was actually submitted to the government" or by alleging facts "based on personal knowledge of billing practices—supporting a strong inference that particular identified claims were submitted," pursuant to *Prather*); *Walgreen*, 846 F.3d at 881 ("In practice, we have applied the 'relaxed' standard just once, and that application has no purchasing power here."). And the Sixth Circuit has found repeatedly that salespeople like Relator, who have no insight into third-party billing procedures, do not qualify. *See Ibanez*, 874 F.3d at 916 ("Relators were sales representatives of BMS and, unlike the relator in *Prather*, did not directly engage with claims whatsoever. In order for the *Prather* exception to apply, it is not enough to allege personal knowledge of an allegedly fraudulent scheme; a relator must allege adequate personal knowledge of billing practices themselves."); *see also Eberhard*, 642 F. App'x at 552–53 (refusing to relax Rule 9(b) standard where relator "was responsible for the sales of [employer's] lab testing services in several states," but could not allege personal knowledge of its claims submissions).

As a salesperson with alleged knowledge of AtriCure's "promotional scheme," but no insight whatsoever into healthcare providers' downstream submission of supposedly fraudulent claims, Relator falls squarely into this Circuit's precedents rejecting the expansion of *Prather*.

II. COUNTS ONE AND TWO MUST BE DISMISSED BECAUSE THE COMPLAINT FAILS TO PLEAD THAT ANY CLAIM FOR PAYMENT WAS FRAUDULENT OR FALSE

Even if the Complaint had identified a claim for payment, dismissal would still be required because the Complaint has not pleaded that any such claim was fraudulent or false. Relator alleges that Defendants violated the FCA because they violated the AKS, arguing that "a claim for payment made pursuant to an illegal kickback is false under the FCA." Compl. ¶ 40. To plead falsity under such a theory, the Complaint must not only state a plausible FCA claim with particularity, but must also state a particularized AKS violation as well. *See, e.g.*, *Antoon*, 978 F. Supp. 2d at 893. In addition, the Complaint must adequately plead that an AKS violation caused the submission of a claim for reimbursement—after all, it is the connection between the illegal kickback and claim for payment that renders a claim for payment fraudulent or false. *See Jones-McNamara*, 630 F. App'x at 400 ("AKS violations can constitute FCA violations where a claim submitted to the government for reimbursement includes items or services resulting from a violation of the AKS.").

Relator has failed to plead a plausible, particularized AKS claim. "To prove a violation of the AKS, Relator must show: (1) remuneration offered or paid; (2) in order to induce the referral of government healthcare business; (3) done knowingly and willfully." *U.S. ex rel. McDonough v. Symphony Diagnostic Servs., Inc.*, 36 F. Supp. 3d 773, 777 (S.D. Ohio 2014). Here, Relator has not adequately pleaded that the bulk of AtriCure's alleged kickbacks constituted illegal remuneration. Relator has not adequately pleaded that any alleged kickback was offered to induce the use or referral of AtriCure devices. And Relator has not even attempted to plead willfulness.

Moreover, Relator has failed altogether to plead causation—the vast majority of alleged kickback recipients are not even alleged to have performed a relevant surgery, much less with the use of an AtriCure device culminating in the submission of a claim. *Cf. Ibanez*, 874 F.3d at 915–16 (holding Section (a)(1)(A) requires a representative claim "tainted" by an alleged kickback scheme and Section (a)(1)(B) requires "a connection between the alleged fraud and an actual claim"). Because the Complaint does not plead a plausible AKS violation, much less one resulting in the submission of a claim, Counts One and Two again must be dismissed.

A. The Complaint does not sufficiently plead illegal remuneration with regard to AtriCure's alleged provision of goods and services

The threshold requirement of an AKS claim is proof that the defendant offered or paid "remuneration." 42 U.S.C. § 1320a-7b(b)(2)(B). Renumeration includes "virtually anything of value," but it does not include "token" gestures of good will, *Jones-McNamara*, 630 F. App'x at 400, or services and products that provide "no substantial independent value to the purchaser," *U.S. ex rel. Suarez v. AbbVie Inc.*, No. 15 C 8928, 2019 WL 4749967, at *7 (N.D. Ill. Sept. 30, 2019) (quoting OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731-01, 2003 WL 2010428, at *23735 (May 5, 2003) ("2003 OIG Guidance")).[6] For example, OIG guidance provides that a laboratory that gives a doctor a free computer, which can only be used to print out test results from the laboratory, has not violated the AKS because the computer has no value independent of the purchased laboratory services. *Id.* at *6 (citing 78 Fed. Reg. 79202-01, 79210 (Dec. 27, 2013)). Similarly, "billing assistance tailored to the purchased

[6] On a motion to dismiss, the Court may consider "(1) any documents attached to, incorporated by or referred to in the pleadings; (2) documents attached to the motion to dismiss that are referred to in the complaint and are central to the plaintiff's allegations, even if not explicitly incorporated by reference; and (3) matters of which the court may take judicial notice." *Antoon*, 978 F. Supp. 2d at 887; *see also United States v. Barnett*, No. 1:19-CR-50-MWM-1, 2020 WL 7062603, at *1 (S.D. Ohio Oct. 9, 2020) ("The Court takes judicial notice of the facts from these publicly available government websites because they are not subject to reasonable dispute and can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.").

products, reimbursement consultation, and other programs specifically tied to support of the purchased product" do not violate the AKS unless they are offered "in tandem with another service or program that confers a benefit on a referring provider (such as a reimbursement guarantee that eliminates normal financial risks)." *Id.* (citing 2003 OIG Guidance).

Attempting still to give the appearance of particularity based on the sheer volume, rather than substance, of its allegations, the Complaint alleges that AtriCure offered healthcare providers illegal remuneration in the form of consulting agreements (Compl. ¶¶ 95–108); free in-kind and promotional services (*id.* ¶¶ 109–32); reimbursement services (*id.* ¶¶ 133–45); grants (*id.* ¶¶ 149–68); and free products and equipment (¶¶ 169–92). AtriCure's publicly-disclosed payments to doctors and institutions for performing clinical studies, training, and other critical services are not illegal remuneration, but rather legitimate professional partnerships. *See id.* ¶ 94 (admitting the Complaint's spreadsheet of remuneration allegedly paid to doctors was pulled from a "publicly available … database"). But, in any event, many of the Complaint's allegations fail on their face to plausibly describe illegal remuneration.

The Complaint alleges, for example, that AtriCure provided reimbursement services to hospitals and physician practices to help "customers secure reimbursement for procedures using AtriCure devices." *Id.* ¶¶ 133–45. The Complaint further alleges that AtriCure provided hospitals with free equipment, such as "generators used to power AtriCure's disposable equipment and cardiac mapping units … used in conjunction with that equipment." *Id.* ¶ 171; *see also id.* ¶ 176 (alleging AtriCure provided unnamed clients with a "service maintenance agreement"); *id.* ¶ 177–79 (alleging that, together with a quote for three AtriCure products, AtriCure offered a free generator and external graphic display PC kit). On the face of the Complaint, these goods and services do not provide any value independent of AtriCure's devices and are no different from a

computer company providing customers with a 1-800 number for resolving technical issues or a free charging cable with the purchase of a laptop. Their value, in other words, relates to the use of the purchased device(s) alone. Consistent with OIG guidance, courts have found that such offerings do not implicate the AKS: "[o]ffering well-supported products might induce physicians to purchase Medtronic products, but only because they are better-supported products than competing products." *U.S. ex rel. Forney v. Medtronic, Inc.*, No. 15-6264, 2017 WL 2653568, at *4 (E.D. Pa. June 19, 2017).

The bulk of the Complaint's remaining allegations fail to plead with particularity the supposed offering of remuneration. With regard to alleged free services, for example, the Complaint often fails to plead who was offered such services, what expenses they otherwise would have incurred, or when. *See, e.g.*, Compl. ¶ 118 (alleging AtriCure "worked to provide content for developing AFib websites" for unspecified "hospitals in Salt Lake City and Denver"); *id.* ¶¶ 113–15 (describing alleged public service announcements), *but see id.* ¶ 121 (noting public services announcements run "2-3 airings per week (free)"); *cf. Suarez*, 2019 WL 4749967, at *9 ("Relator alleges only in a conclusory manner that [free] services eliminated costs that doctors would otherwise have had to cover."); *Forney*, 2017 WL 2653568, at *4 (same). With regard to sponsored events, the Complaint likewise deals largely in vague generalizations, failing to identify who attended such events, what AtriCure paid for them, and in many cases whether they even took place. *See, e.g.*, Compl. ¶¶ 91–93 (describing generic "dinners," but failing to identify their attendees, dates, or value); *id.* ¶ 129 (alleging AtriCure "began the leg work necessary to arrange a dinner" without stating whether it ever happened).

Paragraphs 166–168 are illustrative. There, the Complaint alleges AtriCure "approved an 'education grant' to sponsor an on-demand webcast by five doctors" in early 2016. *Id.* ¶ 166.

While AtriCure sales representatives were purportedly encouraged to "secure the attendance of surgeons and EPs" at the webinar, *id.* ¶¶ 166–68, the Complaint fails to allege where or when the event took place, who attended it, and which five doctors AtriCure supposedly sponsored to speak. *Cf. Jones-McNamara*, 630 F. App'x at 402 ("McNamara did not identify a single employee with authority to make referrals to Life, let alone one who also attended one of Holzer's employee wellness fairs and consumed a Life-sponsored hotdog or hamburger."). At least as to these categories of allegations, the Complaint has not adequately pleaded illegal remuneration.

B. The Complaint does not adequately plead inducement

The second requirement of an AKS claim—and what turns legal remuneration into a kickback—is that the defendant offered remuneration to induce the referral or purchase of the defendant's product. 42 U.S.C. § 1320a-7b(b)(2)(A)-(B); *accord Jones-McNamara*, 630 F. App'x at 400 (noting the "gravamen of Medicare fraud is inducement"); *U.S. ex rel. Nunnally v. W. Calcasieu Cameron Hosp.*, 519 F. App'x 890, 894 (5th Cir. 2013) ("[A]ctual inducement is an element of the AKS violation …. This requires pleading that WCCH knowingly paid remuneration to specific physicians in exchange for referrals."). This criminalizing element cannot be pleaded conclusorily. In other words, it is not enough under either Rule 8 or Rule 9(b) to simply allege that remuneration was offered to "induce" action—a plausible allegation must factually support it. *See Antoon*, 978 F. Supp. 2d at 894 ("[T]he proposed amended complaint merely paraphrases the Anti–Kickback Statute. As such, these paragraphs in the proposed amended complaint are legal conclusions and are unsupported by any additional facts. Therefore, violation of the Anti–Kickback Statute is not pled with the required plausibility."); *see also U.S. ex rel. Perri v. Novartis Pharms. Corp.*, No. CV 15-6547, 2019 WL 6880006, at *17–18 (D.N.J. Feb. 21, 2019) ("Again, this allegation of inducement is conclusory and unsupported by any factual details…. Relator's factual allegations regarding an underlying illegal swap or kickback are insufficient[.]").

The Complaint contains no factual allegations whatsoever that could plausibly support an inference of illegal inducement. On its face, the Complaint describes ordinary—and essential—training, research, and educational initiatives. *See, e.g.*, Compl. ¶ 95 (describing consulting agreements "to provide training and/or educational services"); *id.* ¶ 99 (describing payment for "Training Programs, Meetings and Presentations, Product Development Support, Group Meetings, Sponsored Research Groups"); *id.* ¶ 102 (alleging AtriCure "conducted training events at Defendant St. Helena Hospital" and "paid St. Helena to hold these events"); *id.* ¶ 238 (alleging AtriCure paid travel and lodging "for a program at Defendant St. Helena Hospital").

Not one factual allegation could support even an inference that these payments were shams—*e.g.*, that the alleged trainings and/or educational content did not materialize. *Cf. U.S. ex rel. Bilotta v. Novartis Pharms. Corp.*, 50 F. Supp. 3d 497, 515 (S.D.N.Y. 2014) (alleging defendant hosted lavish "sham speaker events" where "Novartis drugs were not discussed," held events at "Hooters restaurants, and on fishing trips," and in some cases, the events simply "did not take place"). Nor does the Complaint allege any facts whatsoever suggesting that alleged benefits were conditioned upon use or referrals. *Cf. U.S. ex rel. Osheroff v. Tenet Healthcare Corp.*, No. 09-22253, 2012 WL 2871264, at *8 (S.D. Fl. July 12, 2012) ("Relator only alleges in a conclusory fashion that Defendants' remuneration was intended to induce or reward referrals …. There are no factual allegations suggesting any *quid pro quo* of below-fair-market-values leases in exchange for referrals. Neither are there any allegations that any physician-tenants felt pressure to refer patients to Defendants instead of other medical entities … nor allegations that insufficient referral numbers to Defendants would cause or were feared to cause rental rate penalties in future lease renewals.").

Indeed, only Relator's conclusory assertions suggest that these facially legitimate transactions were kickbacks. *See* Compl. ¶ 90 ("AtriCure's business model focuses largely on offering surgeons lucrative agreements to induce them to use AtriCure products when performing AFib procedures."); *id.* ¶ 106 ("AtriCure utilized consulting agreements and free services as vehicles to funnel payments to surgeons in order to induce them to use, or increase their usage of, AtriCure Products."); *id.* ¶ 151 (alleging, without support, that educational grants "w[ere] intended to convince surgeons and EPs, and their hospital affiliates, to use AtriCure products"); *id.* ¶ 152 ("It was commonly known at AtriCure that the giving of grants was directly tied to sales potential."); *id.* ¶ 170 (alleging, without support, that free items were "often given on the explicit condition that the hospital w[ould] predominantly (or exclusively) use AtriCure's products").

Such conclusory assertions do not nudge a complaint from possibility to plausibility. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *accord U.S. ex rel. Laucirica v. Stryker Corp.*, No. 1:09-cv-63, 2010 WL 1798321, at *5 (W.D. Mich. May 3, 2010) (dismissing alleged medical device kickback scheme where conduct described was "neutral on its face and could just as easily support an inference of legality as of illegality"); *U.S. ex rel. Dennis v. Health Mgmt. Assocs., Inc.*, No. 3:09-cv-484, 2013 WL 146048, at *13 (M.D. Tenn. Jan. 14, 2013) (finding claim that defendant paid doctor $60,000, absent additional information about what the doctor's duties were or why that was more than he should have been paid, did not create a reasonable inference that defendant was paying "for referrals instead of for legitimate services"); *Osheroff*, 2012 WL 2871264, at *8 (dismissing complaint that included "no facts to suggest that any physician-tenants were induced by their rent to make referrals based on continued renumeration rather than concern for the health and well-being of each physician's patient").

On balance, the Complaint's AKS allegations could—and do—"just as easily support an inference of legality as of illegality"[7] and thus do "not cross the threshold beyond the mere possibility that a violation of the Anti-Kickback Statute or the False Claims Act occurred." *Laucirica*, 2010 WL 1798321, at *5. The Complaint thus fails across the board to adequately plead a predicate AKS violation.

C. The Complaint does not plead a "knowing and willful" violation of the AKS

In the iterations following his Second Amended Complaint, Relator has withdrawn his FCA claims based on alleged off-label marketing, recognizing correctly that such a theory cannot succeed.[8] But the Complaint nevertheless retains over 40 references to AtriCure's promotion of supposedly off-label procedures. AtriCure's assumption—because Relator has not otherwise attempted to plead the third requirement of an AKS violation—is that the Complaint's continued references to allegedly off-label promotion are an attempt to show that AtriCure's conduct was wrongful. *See, e.g.*, Compl. ¶¶ 5–7, 59, 72; *see also McDonnell v. Cardiothoracic & Vascular Surgical Assocs., Inc.*, No. C2-03-79, 2004 WL 3733402, at *8 (S.D. Ohio July 28, 2004) (explaining that the AKS's "willfulness" requirement necessitates a showing that a defendant acted with the specific "purpose to commit a wrongful act"). This is not even notice pleading as to the AKS's willfulness element. *See Twombly*, 550 U.S. at 555. But, even if it were, Relator's theory still would fail.

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[7] Indeed, to the extent the Complaint's allegations support any inference, it is that AtriCure's payments were perfectly legitimate. For example, the Complaint suggests that alleged relationships, like patient outreach sponsorships, were related to physician and hospital participation in FDA-approved clinical trials—not commercial business practices. *See, e.g.*, Compl. at 24 nn.7–8 (linking to FDA clinical trials website showing that many doctors and hospitals who received alleged remuneration, including Dr. Dunnington and St. Helena, were clinical trial study sites or investigators); *id.* ¶ 130 (noting Porter Adventist was "one of [the] newest DEEP [study] sites" and identifying Drs. Sundaram and Tripathi as investigators).

[8] Earlier versions of Relator's Complaint alleged two bases for FCA liability: (1) that AtriCure allegedly promoted the use of its medical devices in off-label procedures, and (2) that AtriCure allegedly paid kickbacks to healthcare providers in exchange for sales and referrals. In his Third Amended Complaint, Relator abandoned his off-label-promotion claims and has since proceeded on the second basis for liability alone.

As Relator should well understand, there is no such thing as an "off-label procedure." The FDA clears and approves devices—not medical procedures. *See, e.g.*, 21 U.S.C. § 393; *cf.* Compl. ¶¶ 5, 53, 95 (referencing "off-label procedures" or "off-label use of medical procedures"). When a surgeon elects to use a medical device contrary to its labeling in a procedure, it is the use of the specific device, and not the procedure, that is off-label. Accordingly, to the extent Relator's AKS claims are predicated on the promotion and billing of "off-label procedures" as constituting a regulatory violation, Relator is completely off-base.

The Complaint's allegations that AtriCure promoted off-label uses of its devices are doubly deficient, in that they are both impossibly (and likely intentionally) vague and demonstrably false. It is impossible to discern from the Complaint which specific devices Relator believes AtriCure illegally promoted, and why the promoted uses were "off-label." In the transparent hope that all of AtriCure's promotional activities and all of its cardiac ablation devices will come under the Complaint's umbrella, Relator disingenuously lumps every AtriCure product together. *See* Compl. ¶ 68 (alleging generically that "AtriCure improperly and unlawfully promotes its devices off-label for use in [minimally invasive surgery] procedures"), *but see id.* ¶¶ 81–82 (acknowledging AtriCure makes many distinct cardiac ablation devices). And Relator has conveniently omitted any specific device's clearance, choosing instead to baselessly claim that all of AtriCure devices are approved for open-chest surgical ablation only. *See id.* ¶¶ 62, 80 ("AtriCure's devices are not approved, or indicated, by the FDA for use in these [minimally invasive surgery] procedures.").

Unfortunately for Relator, it is well-established that documents integral to the Complaint or subject to judicial notice are properly considered on a motion to dismiss. *Antoon*, 978 F. Supp. 2d at 887. And when those documents "are inconsistent with the allegations of the complaint, the [documents] control[]." *Thomas v. Equifax Info. Servs., LLC*, No. 3:19-CV-286, 2020 WL

1987949, at *5 (S.D. Ohio Apr. 27, 2020); *see also Williams v. CitiMortgage, Inc.*, 498 F. App'x 532, 536 (6th Cir. 2012) (collecting cases).

Every cardiac ablation device that AtriCure manufactures is cleared for use in minimally invasive surgery ("MIS").[9] Specifically, every AtriCure device is cleared for use in "surgery":

- AtriCure's clamps are cleared "for the ablation of cardiac tissue during surgery";[10]
- AtriCure's Isolator Synergy EnCompass Clamp and Guide system is cleared "to ablate cardiac tissue during surgery";[11]
- AtriCure's linear pens are cleared "to ablate cardiac tissue during cardiac surgery";[12]
- The COBRA Fusion devices are cleared "to ablate cardiac tissue during cardiac surgery";[13]
- The Epi-Sense system is cleared "for the coagulation of cardiac tissue . . . using thoracoscopic, endoscopic, and laparoscopic surgical techniques";[14] and
- AtriCure's cryo-ablation probes are cleared for "use in the cryosurgical treatment of cardiac arrhythmias."[15]

The FDA defines cardiac ablation "surgery" as including both "open-chest surgery and minimally

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[9] Consistent with this Court's standard regarding the documents that may be appropriately considered on a motion to dismiss, AtriCure asks the Court to take judicial notice of its devices' public FDA clearances and public FDA Guidance. *See, e.g., U.S. ex rel. Bennett v. Medtronic, Inc.*, 747 F. Supp. 2d 745, 756 & n.9 (S.D. Tex. 2010) (under comparable standard, taking judicial notice of 510(k) premarket notification letter and FDA guidance in dismissing FCA claims based on alleged off-label promotion).

[10] Summary of K211311 510(k) Pre-Market Approval for AtriCure Isolator® Synergy™ Surgical Ablation System, https://www.accessdata.fda.gov/cdrh_docs/pdf21/K211311.pdf.

[11] Summary of K210477 510(k) Pre-Market Approval for Isolator® Synergy™ EnCompass Clamp (OLH, OSH) and Guide (GPM100) System, https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210477.pdf.

[12] Summary of K192125 510(k) Pre-Market Approval for Isolator Transpolar Pen (MAX), https://www.accessdata.fda.gov/cdrh_docs/pdf19/K192125.pdf.

[13] Summary of K190151 510(k) Pre-Market Approval for COBRA Fusion® ablation system https://www.accessdata.fda.gov/cdrh_docs/pdf19/K190151.pdf.

[14] Summary of K142084 510(k) Pre-Market Approval for EPi-Sense Guided Coagulation Device with VisiTrax, https://www.accessdata.fda.gov/cdrh_docs/pdf14/K142084.pdf.

[15] Summary of K200697 510(k) Pre-Market Approval for AtriCure® cryoICE® cryoablation probe (Cryo2), https://www.accessdata.fda.gov/cdrh_docs/pdf20/K200697.pdf. The Cryo2, cryoICE and cryo-ablation probes are also "intended for use to temporarily block pain by ablating intercostal nerves under direct visualization in adolescent patients of at least 12 years of age," and "Direct visualization, in this context, requires that the surgeon is able to see the targeted tissue for cryoablation directly or with assistance from a camera, endoscope or other similar optical technology." *Id.*

invasive surgery via thoracoscopy, as long as the clinician performs the majority of the ablation lesions under direct visualization." FDA's Final Guidance for Industry and Food and Drug Administration Staff: Clinical Study Designs for Surgical Ablation Devices for Treatment of Atrial Fibrillation (Feb. 15, 2013). "[D]irect visualization … means that the clinician is able to see, either directly or by means of live video, the point or area of epicardial and/or endocardial contact[.]" *Id.*; *cf.* Compl. ¶¶ 61–62 (acknowledging "MIS" procedures involve a surgeon "perform[ing] the surgery with the benefit of an endoscope" and "using a television monitor for visualization"). Accordingly, the Complaint's allegation that AtriCure's devices are approved for open-chest procedures alone is flatly contradicted by public FDA documents and not entitled to any assumption of truth. *Williams*, 498 F. App'x at 536.

Because the promotion of AtriCure's devices for use in MIS approaches to cardiac ablation—whether standalone or hybrid—is entirely consistent with FDA-sanctioned labeling, the Complaint's off-label marketing allegations are facially implausible and cannot demonstrate alleged "willfulness." *See, e.g.*, *Bennett*, 747 F. Supp. 2d at 756 & n.9 (taking judicial notice of 510(k) premarket notification letter and FDA guidance and dismissing FCA claims based on alleged off-label promotion).[16]

D. The Complaint does not adequately plead that an AKS violation resulted in a claim for payment

In addition to pleading a particularized AKS violation, a FCA complaint premised on the AKS must plead the requisite connection between that violation and the submission of claims. The connection is a necessary element of both Counts One and Two of the Complaint, and "must be

[16] For the same reasons, the Complaint's assertion that AtriCure's conduct fell outside the statutory safe harbors to AKS liability fails on its face. *See* Compl. ¶¶ 36–49. The only reason Relator provides for their non-application is that AtriCure was ineligible by virtue of alleged off-label marketing—which is facially false. *See id.* ¶ 42 (alleging "personal services" safe harbor does not apply when "conditioned on off-label use"), *id.* ¶ 46 (alleging "discounts" safe harbor does not apply "when conditioned on off-label use").

evident. Otherwise, a cause of action under the FCA for fraud directed at private entities would threaten to transform the FCA into an all-purpose antifraud statute." *Ibanez*, 874 F.3d at 915–16 (holding Section (a)(1)(A) requires a representative claim "tainted" by an alleged kickback and Section (a)(1)(B) requires "a connection between the alleged fraud and an actual claim"). As the Third Circuit has explained:

> A kickback does not morph into a false claim unless a particular [person] is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that [person]. Even if we assume [defendant] paid illegal kickbacks, that is not enough to establish that the underlying medical care … was connected to a breach of the Anti-Kickback Statute; we must have some record evidence that shows a link between the alleged kickbacks and the medical care received[.]

U.S. ex rel. Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 100 (3d Cir. 2018). More recently, the Eighth Circuit has held it is not enough simply to allege such a link—rather, a plaintiff basing a FCA claim on an alleged AKS violation "must prove that a defendant would not have included particular items or services but for the illegal kickbacks." *U.S. ex rel. Cairns v. D.S. Med. LLC*, No. 20-2445, 2022 WL 2930946, at *4, 6 (8th Cir. July 26, 2022) (relying on Supreme Court precedent to conclude that the "common and ordinary usage" of "resulting from … expresses a but-for causal relationship" and that "[i]t is textbook tort law that an action is not regarded as a cause of an event if the particular event would have occurred without it").

The Complaint falls short as to both standards. As a threshold matter, because the Complaint fails to identify any claim for payment, it necessarily fails to identify a claim for payment resulting from an alleged bribe. *Cf. Walgreen*, 846 F.3d at 881 (without identifying customers who "filled any prescriptions at Walgreens at all, let alone that Walgreens processed them and filed reimbursement claims with the government," it was immaterial that Walgreens allegedly induced Medicaid/Medicare customers to use its pharmacies). Moreover, the Complaint also fails to link any alleged bribe to the submission of a supposed claim. Most of the physicians

who are alleged to have received kickbacks from AtriCure are not alleged to have performed a procedure using an AtriCure device—or even to live in a jurisdiction where AtriCure is alleged to have made sales. The Complaint thus fails to adequately allege that a particular claim "resulted from" a violation of the AKS.

1. Alleged "Kickbacks to Individual Providers" (Compl. ¶¶ 90–145)

In a chart based on "publicly available" data, the Complaint identifies 23 doctors who received payments from AtriCure between 2013 and 2018. Compl. ¶ 94 & n.11. Eleven of the 23 doctors are never mentioned in the Complaint again—in any capacity: Drs. Gerdisch, Olsen, Kiser, Johnkoski, Damiano, Whalen, Chang-Sing, Svinarich, Reeves, Mahan, and Connors. Ten other doctors allegedly received kickbacks, but are not even alleged to have performed a surgery using an AtriCure device, let alone one that supposedly resulted in a claim for payment: Drs. Dunnington, Khoynezhad, Eifling, DiGiorgi, Bell-Thomson, Beaver, Affleck, Sperling, Mehall, and Doty.[17] Thus, while these allegations add volume to the Complaint, they plainly fail to allege the requisite connection between alleged AKS and FCA violations. *Cf. U.S. ex rel. Petkovic v. Founds. Health Sols., Inc.*, No. 5:10-CV-2846, 2019 WL 251556, at *9 (N.D. Ohio Jan. 17, 2019) (dismissing FCA complaint that, *inter alia*, described alleged kickbacks to one population and alleged claims for payment submitted by another).

As to the two remaining doctors, Drs. Tripathi and Kumpati, the only allegations linking a supposed AKS violation to the potential submission of a claim are Relator's new allegations, discussed in Section I.A above. *See* Compl. ¶¶ 238–40 (alleging Dr. Tripathi received $1,877 from

[17] The Complaint's "Kickbacks to Individual Providers" section references a handful of additional healthcare providers beyond the 23 identified in Paragraph 94, but those doctors likewise are not alleged to have performed any surgery with an AtriCure device. *See id.* ¶ 124 (Dr. Robinson); ¶¶ 128–31 (Dr. Sundaram); *id.* ¶ 141 (alleging AtriCure's billing specialist communicated with a Colorado practice about a procedure that Drs. Stout and Glatterer "would like to do")—*but see id.* ¶ 142 (alleging the billing specialist consulted on what was allowed by "most insurance companies"—not CMS).

AtriCure in 2014 and performed one surgery using AtriCure devices on a Medicare-eligible patient later that year, without any factual allegations confirming a claim resulted); *id.* ¶¶ 242–46 (alleging Dr. Tripathi received further kickbacks from AtriCure in 2015 and "scheduled" two surgeries with Medicare-eligible patients, without any allegations concerning the use of an AtriCure device or confirmation that the surgeries happened); *id.* ¶¶ 248–49 (alleging Dr. Kumpati received $1,910 from AtriCure in 2014 and performed one surgery on a Medicare-eligible patient using AtriCure devices in 2015, without any factual allegations that would suggest a claim resulted); *id.* ¶ 254 (alleging Dr. Kumpati "scheduled" a further surgery at a VA hospital in 2015, without any allegation that the surgery happened, or in fact used a "pre-authorized" AtriCure device, or any particulars regarding a theoretically resulting claim).

In other words, in over 150 paragraphs describing scattershot—and perfectly legitimate—interactions between AtriCure and individual doctors, the Complaint at best alleges that two doctors possibly could have caused the purchase of an AtriCure device that possibly could have resulted in the submission of a tainted claim, simply by virtue of alleging those doctors did their jobs (*i.e.*, performed/scheduled heart surgeries). Obviously, that is not enough to allege a FCA claim "from one end of this scheme—defendants' improper promotion—to the other—claims for reimbursement." *Ibanez*, 874 F.3d at 915. Nor does it remotely meet the standard for pleading with particularity. *See Sanderson*, 447 F.3d at 878 ("Clearly, what is alleged in the complaint before us is limited to speculation and unsupported conclusion ... the district court was correct in finding that these allegations failed to satisfy Rule 9(b)."). The Complaint has, therefore, failed to allege a FCA claim resulting from alleged kickbacks to any individual.

E. Alleged "Kickbacks to Institutions" (Compl. ¶¶ 146–192)

The Complaint's allegations regarding alleged kickbacks to institutional providers fare no better. In nearly 50 paragraphs, the Complaint identifies one institution that supposedly received

a kickback from AtriCure and also might possibly have submitted a claim. *See* Compl. ¶¶ 181–82, 187–92 (describing alleged kickbacks to Porter Adventist); *id.* ¶¶ 239, 244–45 (describing one alleged surgery and two "scheduled" surgeries at Porter Adventist). Notably, the only surgery at Porter Adventist alleged to have (1) actually taken place and (2) used an AtriCure device predated any alleged kickbacks to the hospital. *See id.* ¶¶ 239–40 (describing AtriCure products allegedly used in a December 18, 2014 procedure); *but see id.* ¶¶ 181–82, 187–92 (describing alleged kickbacks to Porter Adventist in 2015). Thus, even if Porter Adventist had submitted a claim for payment in connection with that surgery—and for the reasons discussed above, a bald allegation that a patient was Medicare-eligible does not support a viable inference that it did—that claim could not have resulted from any alleged kickback to the institution. The Complaint thus altogether fails to allege that AtriCure offered to bribe any institution, resulting in a specific procedure using an AtriCure device, resulting in the submission of a claim. *Cf. Ibanez*, 874 F.3d at 915 ("In order to survive defendants' motion, relators must provide a representative claim that describes each step with particularity: a prescription reimbursement submitted to the government for a tainted prescription of Abilify.").

Because the Complaint fails to link any healthcare provider to any claim for payment resulting from an alleged kickback, Counts One and Two again must be dismissed.

III. COUNT TWO MUST BE DISMISSED FOR THE ADDITIONAL REASON THAT THE COMPLAINT FAILS TO IDENTIFY ANY FALSE RECORD

The FCA's false records provision (Count Two) imposes liability on anyone who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B). False records are thus distinct from false claims and must separately be identified with particularity. *See, e.g., U.S. ex rel. Kustom Prods., Inc. v. Hupp & Assocs., Inc.*, No. 2:15-CV-03101, 2017 WL 2021512, at *5 (S.D. Ohio May 12,

2017) ("As with a claim under other provisions of § 3729, a claim for relief under § 3729(a)(1)(B), to survive Rule 9(b) scrutiny, must provide sufficient detail regarding the time, place and content of the defendant's alleged false statements and the claim for payment."). Attempting to plead a false records claim "based on identical conduct" to that alleged under Section (a)(1)(A) does not suffice. *Id.*; *see also U.S. ex rel. Roycroft v. Geo Grp., Inc.*, 722 F. App'x 404, 406 n.1 (6th Cir. 2017) (disregarding false records claim where relator's claim was premised "on the presentment of false claims, not the making of separate false records or statements material to those claims").

As "Background" information, the Complaint alleges generally that providers must enroll to participate in Medicare and Medicaid, and that the application process requires a certification that providers will comply with applicable laws. *See* Compl. ¶¶ 25, 29. But the Complaint does not allege the "time, place and content" of any such certification by any specific healthcare provider, and certainly does not allege that AtriCure somehow caused such a certification to be submitted. *Cf. Sanderson*, 447 F.3d at 877. Nor does the Complaint identify any other supposedly false record in support of its Section (a)(1)(B) theory. The Complaint's rote recitation of the elements of a false records claim must, therefore, be disregarded. *See, e.g.*, *Petkovic*, 2019 WL 251556, at *4 n.2 (dismissing claim where "relators cite the language of § 3729(a)(1)(B)," but the "complaint is completely devoid of any allegations that [defendant] made any false statements connected to any claims submitted to the government"); *Kustom Prods.*, 2017 WL 2021512, at *5 (dismissing Section 3729(a)(1)(B) claim where allegation that defendant "certified to the government that its shipments conformed to all contract requirements" was "wholly lacking any factual development").

IV. COUNT THREE MUST BE DISMISSED BECAUSE THE COMPLAINT FAILS TO ALLEGE A CONSPIRACY TO VIOLATE THE FCA

Count Three of the Complaint, Relator's conspiracy claim, "falls with the two preceding

substantive claims." *Wal-Mart*, 858 F. App'x at 879. "Conspiracy under the FCA is derivative of the substantive claims of submitting a false claim to the government or creating a false record." *Id.* Thus, Relator's failure to "meet the pleading standards of Rules 12(b)(6) and 9(b)" as to Counts One and Two "means his conspiracy claim fails as well." *Id.* at 880; *see also Crockett* 721 F. App'x at 459 ("[Relator]'s lack of specification as to the existence of any false claim also precludes her false-claims-conspiracy count."); *Sharma*, 472 F. Supp. 3d at 447 ("As with Relator's other FCA fraud claims, there is no specific identification of a particular claim improperly made to the government by virtue of Defendants' alleged conspiracy.")

Count Three also fails because the Complaint has not adequately pleaded the existence of an agreement between the Defendants to violate the FCA. Section 3729(a)(1)(C) "requires a relator to plead facts showing that there was a plan or agreement to commit a violation of one or more of the FCA subsections"—in other words, "a plan to get false claims paid." *Ibanez*, 874 F.3d at 917. At best, the Complaint has described a plan to promote awareness of surgical Afib intervention and, by extension, to sell more AtriCure devices. But that describes normal and legal business activity, and "does not amount to a conspiracy to violate the FCA. Even if it was foreseeable that somewhere down the line [false claims] would be submitted to the government for payment, that foreseeable consequence does not subsume the aim of the agreement." *Id.* "In other words, to adequately allege an FCA conspiracy, it is not enough for relators to show there was an agreement that made it likely there would be a violation of the FCA; they must show an agreement was made in order to violate the FCA." *Id.* Because the Complaint does not allege an agreement between AtriCure and anyone else to violate the FCA, Count Three must be dismissed.

V. COUNTS FOUR THROUGH THIRTY-SEVEN MUST BE DISMISSED BECAUSE THE COMPLAINT FAILS TO ALLEGE VIOLATIONS OF STATE AND LOCAL LAWS

The Complaint's state and local law claims fail for the same reasons as its federal FCA

claims, in addition to the fact that the Complaint simply fails to plead any conduct at all in the vast majority of the relevant jurisdictions. Even if any state or local law claim were independently plausible, however, the Court should decline to exercise supplemental jurisdiction over them.

A. The Complaint fails to plead any conduct in most states and municipalities

Counts Four through Thirty-Seven of the Complaint make conclusory allegations of violations of various state and local equivalents of the federal FCA. Twenty-seven of those counts must be dismissed because the Complaint does not include any conduct whatsoever in the relevant jurisdiction: Connecticut (Count Six), Delaware (Count Seven), Georgia (Count Nine), Illinois (Count Eleven), Indiana (Count Twelve), Iowa (Count Thirteen), Louisiana (Count Fourteen), Maryland (Count Fifteen), Massachusetts (Count Sixteen), Michigan (Count Seventeen), Minnesota (Count Eighteen), Montana (Count Nineteen), Nevada (Count Twenty), New Hampshire (Count Twenty-One), New Jersey (Count Twenty-Two), New Mexico (Count Twenty-Three), New York (Count Twenty-Four), Oklahoma (Count Twenty-Six), Rhode Island (Count Twenty-Seven), Tennessee (Count Twenty-Eight), Texas (Count Twenty-Nine), Vermont (Count Thirty), Virginia (Count Thirty-One), the District of Columbia (Count Thirty-Three), the County of Allegheny (Count Thirty-Four), City of Chicago (Count Thirty-Five), City of New York (Count Thirty-Six), and City of Philadelphia (Count Thirty-Seven).

B. The remaining state law claims are coextensive with the federal claims

Even if the Court were to assume that the Complaint alleges sufficient conduct in the remaining jurisdictions to support a claim—and it does not[18]—those claims should be dismissed for the same reasons as Counts One through Three. A failure to state a claim under the federal

[18] The sum total of the Complaint's North Carolina-based allegations, for example, are that a single advisory board meeting took place in Chapel Hill, North Carolina. *See* Compl. ¶¶ 199–200. That allegation is not even purportedly tied to any supposed kickback, surgery, or claim for payment.

FCA dooms claims brought under each of the relevant state and local analogs. *See U.S. ex rel. Mosler v. City of Los Angeles*, 414 F. App'x 10, 11 (9th Cir. 2010) (affirming dismissal of both federal and state FCA claims because "California analogue is nearly identical" to federal FCA); *Colorado v. Kindred Healthcare, Inc.*, No. 15-CV-02759-CMA, 2021 WL 1085423, at *5 n.1 (D. Colo. Mar. 22, 2021) ("Given the substantial similarities between the FCA and the [Colorado Medicaid False Claims Act], the Court's analysis applies equally to Ms. Lovato's CMFCA claims."); *U.S. ex rel. Sharpe v. Americare Ambulance*, No. 8:13-CV-1171-T-33AEP, 2017 WL 2840574, at *7 (M.D. Fla. July 3, 2017) (dismissing claims under Florida FCA because parallel federal claims did not suffice); *U.S. ex rel. Woodruff v. Hawaii Pac. Health*, 560 F. Supp. 2d 988, 997 (D. Haw. 2008), *aff'd sub nom. U.S. ex rel. Hawaii v. Hawaii Pac. Health*, 409 F. App'x 133 (9th Cir. 2010) ("[T]he court applies the same analysis for liability under the federal and state FCA."); *U.S. ex rel. Gugenheim v. Meridian Senior Living, LLC*, No. 5:16-CV-410-BO, 2020 WL 1932435, at *4 (E.D.N.C. Apr. 21, 2020), *aff'd*, No. 20-1583 (4th Cir. May 26, 2022) ("[T]he North Carolina False Claims Act is to be interpreted consistently with the federal False Claims Act. N.C. Gen. Stat. § 1-616(c). Accordingly, the Court's discussion of the False Claims Act applies to relator's federal and state law claims."); Claire M. Sylvia, Washington: Medicaid Fraud False Claims Act, *The False Claims Act: Fraud Against the Government* § 12:86 (June 2022 Update) (noting Washington's Medicaid Fraud False Claims Act is "patterned after the federal Act").

C. The Court should decline supplemental jurisdiction in any event

Finally, even if any state or local claim could somehow withstand dismissal, there is no reason for the Court to exercise jurisdiction over them. "Ordinarily, where all federal claims have been dismissed, federal courts should decline to exercise supplemental jurisdiction over state law claims." *Reynosa v. Schultz*, 282 F. App'x 386, 391 (6th Cir. 2008); *accord Antoon*, 978 F. Supp.

2d at 894 ("When all federal claims are dismissed before trial, the balance of considerations usually will result in dismissal of the state-law claims. That would be the case here.").

VI. THE COMPLAINT SHOULD BE DISMISSED WITH PREJUDICE

This is Relator's fifth attempt to state a viable claim for relief, including his most recent amendment, which was undertaken specifically to address this Circuit's stringently-enforced Rule 9(b) standards. Relator's complete and consistent failure to identify an actual false claim with particularity demonstrates the obvious—he cannot. As *Prather* makes clear, a salesperson at Company A with no knowledge about the billing practices of Company B simply cannot make the necessary link between alleged conduct on the one hand and the theoretical submission of tainted claims on the other. Because no amendment can change this fundamental shortcoming in Relator's allegations, any further amendment would be futile, and the Complaint should be dismissed with prejudice. *See Layer-Rosario v. Allied Mortg. Cap. Corp.*, No. 17-5468, 2018 WL 1989636, at *3 (6th Cir. Jan. 9, 2018) ("Amendment of a complaint is futile when the proposed amendment would not permit the complaint to survive a motion to dismiss."); *Daniels v. Morgan Asset Mgmt., Inc.*, 497 F. App'x 548, 555 (6th Cir. 2012) ("[B]ecause this proposed amendment would be Plaintiffs' third failed attempt to file an action that is not precluded by SLUSA, the district court did not abuse its discretion in dismissing Plaintiffs' suit with prejudice.").

CONCLUSION

For the foregoing reasons, Relator's Complaint should be dismissed with prejudice.

Dated: August 17, 2022

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 17, 2022, a copy of the foregoing was electronically filed with the Clerk of Court using the Court's electronic filing system. Notice of this filing will be sent to counsel of record by operation of the Court's electronic filing system, and the parties may access the filing through the Court's system.

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